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SEP 30 1996

A/14

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Arlington, VA 22201

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,364,921

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,364,921, which claims the human drug product, ULTRAVIST®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of October 25, 1995 (60 Fed. Reg. 54,694). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,353) + 1,165 \\ &= 1,842 \text{ days (5.05 years)}\end{aligned}$$

Since the regulatory review period began June 19, 1988, after the patent issue date (December 21, 1982), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(B) applies in the present situation because the patent was issued before the date of enactment (September 24, 1984) of 35 U.S.C. § 156 and since no request for an exemption under subsection 505(i) of the Food, Drug and Cosmetic Act was submitted before the date of enactment. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(B), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for

a period of five years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,364,921
Granted:	December 21, 1982
Original Expiration Date:	March 6, 2000
Applicant:	Ulrich Speck, et al.
Owner of Record:	Schering Aktiengesellschaft
Title:	Novel Triiodinated Isophthalic Acid Diamides as Nonionic X-Ray Contrast Media
Classification:	424/9.454
Product Trade Name:	ULTRAVIST®
Term Extended:	Five Years

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.

H. Bernstein

Hiram H. Bernstein  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: ULTRAVIST®  
FDA Docket No.: 95E-0260  
[Attorney Docket No. BERLX 208X]